STUDY PROTOCOL

A protocol for a systematic review of behaviour change techniques used in the context of stillbirth prevention

[version 2; peer review: 2 approved, 1 approved with reservations]

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Abstract

Background: Stillbirth is a devastating pregnancy outcome that affects approximately 3.5 per 1000 births in high-income countries. Previous research has highlighted the importance of focusing prevention efforts on targeting risk factors and vulnerable groups. A wide range of risk factors has been associated with stillbirth before, including maternal behaviours such as back sleep position, smoking, alcohol intake, illicit drug use, and inadequate attendance at antenatal care. Given the modifiable nature of these risk factors, there has been an increase in the design of behaviour change interventions targeting such behaviours to reduce the risk of stillbirth.

Objectives: The aim of this study is to identify all behavioural interventions with a behavioural component designed and trialled for the prevention of stillbirth in high-income countries, and to identify the behaviour change techniques (BCTs) used in such interventions using the Behaviour Change Techniques Taxonomy V1 (BCTTv1).

Inclusion criteria: Interventions will be included in this review if they (1) have the objective of reducing stillbirth rates with a focus on behavioural risk factors; (2) are implemented in high-income countries; (3) target pregnant women or women of childbearing age; and (4) are published in research articles.

Methods: A systematic search of the literature will be conducted. The results of the search will be screened against our inclusion criteria by two authors. The following data items will be extracted from the selected papers: general information, study characteristics, participant...
and intervention/approach details. The Cochrane Effective Practice and Organization of Care (EPOC) risk of bias criteria will be used to assess the methodological quality of included studies. Intervention content will be coded for BCTs as present (+) or absent (-) by two authors using the BCTTv1, discrepancies will be discussed with a third author. A narrative synthesis approach will be used to present the results of this systematic review.

**Keywords**
stillbirth, intervention, behaviour change, risk factors

This article is included in the Maternal and Child Health collection.
Amendments from Version 1

This manuscript has been updated to reflect the reviewers’ suggestions:

- Further detail has been added to the introduction section to strengthen the justification of why this review is needed and how it is different from the previous Cochrane review published by Ota et al.
- The PROSPERO ID has been added to the protocol section.
- A sentence has been added to the eligibility criteria section to strengthen the justification of focusing the review on high-income countries.
- Changes in rates of stillbirth have been added as an outcome in the PICO framework table. Studies that do not include stillbirth (or perinatal death) as one of their outcomes will not be included.
- A description of how the manual search will be conducted has been added to the selection process section.
- A second risk of bias tool has been proposed to make sure all types of studies are covered, as per one of our reviewers’ suggestions.
- Further description has been added to the data synthesis section and BCT coding to explain how the data will be treated.

Any further responses from the reviewers can be found at the end of the article

Abbreviations
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; BCT: Behaviour Change Technique.

Introduction
Stillbirth is one of the most devastating outcomes of pregnancy that expectant parents can face. In Ireland, a stillbirth is defined as an infant born weighing 500 grams or more or at a gestational age of at least 24 weeks who shows no signs of life. However, this definition of stillbirth is not globally accepted, with different countries using different weight or gestational thresholds, ranging from 350 grams to 1000 grams and from 20 weeks to 28 weeks. The worldwide estimates of stillbirth rates in 49 high-income countries at 28 weeks gestation was 3.5 per 1,000 total births in 2015, with country-specific rates varying from 1.3 in Iceland to 8.8 in Ukraine. In Ireland, the latest data published by the National Perinatal Epidemiology Centre shows that the prevalence of stillbirth was 3.8 per 1,000 births in 2017.

The stillbirth series published in the Lancet in 2016 highlighted the importance of focusing future stillbirth prevention efforts in high-income countries on targeting specific causes, risk factors, and vulnerable groups. In high-income countries, the majority of stillbirths occur prior to labour and are associated with placental pathology. However, previous research has shown that stillbirth is associated with a wide range of risk factors, including maternal medical factors, for example hypertensive disorders or diabetes; factors associated with the woman’s obstetric history, for example having a history of previous pregnancy loss, primiparity or multiple pregnancy; pregnancy related complications such as placental insufficiency or fetal growth restriction; ethnic and socioeconomic status; maternal overweight and obesity; and maternal age.

Maternal behavioural risk factors include factors such as sleep position, smoking, alcohol intake, illicit drug use, and inadequate antenatal care. Such behavioural risk factors are modifiable and so provide useful targets for stillbirth prevention interventions.

Considering that some of the mentioned maternal behavioural risk factors have the potential to be modified, there has been an increase in development and implementation of antenatal behavioural interventions targeting those behaviours to reduce the risk of stillbirth. Behavioural interventions are defined here as those targeting behaviours such as smoking cessation interventions, midwifery led care, birth attendant training, alternative packages of antenatal care and diet and exercise interventions. However, in an overview of 43 Cochrane reviews assessing 61 different stillbirth prevention approaches across the globe, few reviews were found to produce clear evidence as the effectiveness of interventions differed across settings, highlighting the importance to understand the intervention’s context. Further, this Cochrane review of reviews had a focus on a broad range of interventions (i.e., nutritional interventions, prevention and management of infection, prevention and management of morbidities, screening and management of fetal growth), not only those with a behaviour change component.

To date, there has not been any systematic review of behaviour change interventions conducted in the context of stillbirth prevention. Hence, this review is important to understand what techniques have been used previously to inform the development of theoretically robust evidence based interventions.

Previous studies have been conducted to explore facilitators and barriers influencing health behaviours during pregnancy. Identifying and synthesising all existing behaviour change interventions designed in the context of stillbirth prevention, combined with the information obtained from the literature exploring factors influencing behavioural risk factors, will inform the development of new strategies applicable in high-income countries. Given the variability across definitions, outcomes and measures of stillbirth, and the potential for differential intervention approaches to be used, there is a need to identify and synthesise the different components, or behaviour change techniques (BCTs), used in such interventions. A BCT is an observable, replicable and irreducible component of an intervention, an “active ingredient”, designed to alter or redirect casual processes that regulate behaviour. Identification of BCTs in interventions allows for accurate replication of interventions and faithful implementation of interventions demonstrating effectiveness. Hence, knowing which specific BCTs have been used within interventions is important to build cumulative evidence towards delivering effective and replicable interventions in this context. Additionally, reviewing and identifying BCTs in stillbirth prevention interventions will also enable future investigations of links between BCTs and...
mechanisms of action that will facilitate the optimisation of intervention effectiveness.

To our knowledge, there has been no systematic examination of BCTs used in behaviour change interventions designed with the objective to reduce stillbirth risks. Such a review is essential to informing and improving the development of future stillbirth prevention interventions. This review will build on previous reviews of general stillbirth prevention interventions (including infection management, pharmacotherapy for prevention of pre-eclampsia, screening for diabetes, ultrasound in early and late pregnancy, antenatal cardiotocography for fetal assessment), such as the one conducted by Ota and colleagues, by focusing on those interventions with a behavioural component and by aiming to identify the BCTs used within those interventions.

The aim of this systematic review is to identify all research studies examining behaviour change interventions used in the context of stillbirth prevention within high-income countries, and to synthesise the BCTs used in these interventions.

Objectives
- To identify behavioural interventions used for the prevention of stillbirth in high-income countries.
- To identify and code the BCTs used in such interventions using the Behaviour Change Techniques Taxonomy V1 (BCTTv1).

Protocol
Details of this review have been submitted for registration to the PROSPERO database (ID CRD42021264914). Amendments made to the protocol will be acknowledged on PROSPERO and in any publications following this study. This protocol has been informed by the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines for the reporting of systematic reviews.

Eligibility criteria
The “PICO” framework was used to select inclusion and exclusion criteria for this review (Table 1). For the purpose of this review, we did not select any specific definition for stillbirth because, as noted, definitions differ internationally.

The following study types are eligible for inclusion: case-control studies, randomised control trials, cross-sectional studies, and quasi experimental studies. Studies will be eligible for inclusion when published in high-income countries given the differences between care systems and the challenges associated with improving pregnancy outcomes amongst low-, middle- and high-income countries. Additionally, focusing this study in high-income countries only will facilitate the use of its findings to develop behaviour change strategies applicable to such contexts. High-income countries will be defined based on the World Bank Country Classification (Gross National Income per capita of $12,696 or more in 2020). The findings of this systematic review will help inform the development of an intervention to be used in a high-income country setting.

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<tr>
<th>Table 1. PICO framework.</th>
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<td><strong>PICO framework</strong></td>
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Information sources
A systematic literature search covering all interventions in the context of stillbirth prevention from inception to present will be performed in the following databases: CINAHL Complete, SocIndex, Web of Science, PubMed, PsycINFO and Open Grey. Searches in Open Grey and contact with authors will facilitate access to non-published articles. Additionally, we will also conduct a manual reference list searching of the identified articles.

Search strategy
Keyword searches will be used across four different concepts (1) Stillbirth, (2) Intervention, (3) Pregnancy and (4) Study design. The search strategy was developed for PubMed (see Table 2) but it will be adapted depending on the database in combination with database-specific filters.

Study records
Data management
Studies will be imported into Endnote, duplicates will be identified by using the automatic “Check for Duplicates” tool, as well as manually screening the results. The screening of titles will be conducted using Rayyan, which is a web platform for systematic reviews.

Selection process
Two independent reviewers (TES, KMS) will individually screen titles, abstracts, and full articles to identify eligible studies, using our inclusion and exclusion criteria. In cases of uncertainty in title and abstract screening, studies will be included in the full text review stage. When identifying systematic reviews, a manual search of their included interventions will be conducted to ensure that all relevant interventions are included.
### Table 2: Example of search.

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<th>Database: Pubmed</th>
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<th>Search Terms</th>
<th>Search Results</th>
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<td><strong>Concept 1 Stillbirth</strong></td>
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<td>TI/AB Stillbirth</td>
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<td>TI/AB Perinatal death</td>
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<td><strong>Concept 2 Intervention</strong></td>
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<td>TI/AB Health promotion</td>
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<td>TI/AB Behavior</td>
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<td>TI/AB Behaviour Change</td>
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<td>TI/AB Intervention</td>
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<td><strong>Concept 3 Pregnancy</strong></td>
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<td>TI/AB Pregnant women</td>
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<td>TI/AB Pregnancy</td>
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<td>TI/AB Childbearing age</td>
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<td>TI/AB Prenatal</td>
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<td>TI/AB “Randomized controlled trial”</td>
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<td>TI/AB “control group”</td>
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<td>TI/AB “controlled trial”</td>
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<td>30. TI/AB “case-control study”</td>
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<td>31. TI/AB “quasi-experimental”</td>
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<td>32. TI/AB Initiative</td>
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<td>33. TI/AB Guideline</td>
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<td>35. S5 AND S18 AND S24 AND S34</td>
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Limiters: - Humans

in this review. We will also perform a further manual citation search of included studies. Discrepancies will be resolved through consensus discussion and/or recourse to a third reviewer.

A PRISMA flow diagram will be used to show process of study screening and summarise the inclusion and exclusion criteria at each stage of the review.

#### Data collection process

Once the final list of studies to include in the review has been determined, all supplementary materials or additional studies related to the same intervention will be retrieved by TES before data extraction or quality assessments. When direct access is not provided to these supplementary materials online, the original study authors will be contacted to request these materials. Published manuscripts of trial outcomes and intervention protocols will be examined for intervention details.

#### Data items

A structured data extraction sheet using Microsoft Word will be used to extract the study characteristics (see Extended data), which will be piloted in advanced. Data will be extracted by one reviewer (TES) and verified for accuracy by another reviewer (KMS).

Study characteristics to be extracted include:

1. General information: Authors, title, name of intervention/approach (if applicable), year of publication, country of origin.
2. Study characteristics: Study aims/objectives, type of study/report, stillbirth definition used, recruitment strategy.
3. Participants: cohort size, number of people in control arm (if applicable), number of people in intervention arm (if applicable), mean age, age range, socio-economic status, education level, ethnicity, pregnancy status, relationship status.
(4) Intervention/approach details: setting, investigated topic/ target behaviour, description of intervention/approach and control treatments, delivery mode, intervention duration, current stage of implementation, outcomes measured in intervention (e.g. reduction stillbirth rates, increased awareness, behaviour change), effectiveness of intervention.

Outcomes and prioritization
Primary outcome:
- BCTs used (as described in the BCTTv1)

BCT coding
The coding of the BCTs included in the identified interventions/approaches will be conducted following the BCTTv1 approach. Intervention content will be coded for presence (+) or absence (-) of the BCTs. This process will be done by two authors independently (TES, KMS) and discussion and comparison will be used to address any discrepancies. A third member of the research team (MB) will be consulted in case of disagreement. The findings of the BCT coding will be presented in tabular format. To examine the use of BCTs in the interventions, the percentage of individual BCTs across studies and the total number of BCTs per intervention will be calculated. Additionally, we will tabulate the identified BCTs in order to identify patterns across the different studies.

Risk of bias in individual studies/quality assessments
The Cochrane Effective Practice and Organization of Care (EPOC) risk of bias criteria will be used to assess the methodological quality of the included studies that will subsequently feed into the GRADE process.

The Joanna Briggs Institute (JBI) critical appraisal checklist will be used for both descriptive and analytical cross-sectional studies.

Data synthesis
We anticipate that a meta-analytic approach would be inappropriate for comparison of studies due to the potential high heterogeneity of the interventions and potential BCTs. Hence, we will use a narrative synthesis approach as recommended by Cochrane when a meta-analytical approach is not possible, to summarise the findings of BCTs. Studies will be grouped based on the behaviour they focus on. The results of the studies will be systematically examined by summarising the same features of each study using pre-designed data extraction sheets. The findings will also be presented in tabular form. This approach will facilitate the description of the interventions and BCTs used, taking into account quality appraisals.

Analysis of subgroups or subsets
While subgroup analyses may be undertaken, it is not possible to specify the groups in advance.

Dissemination
The PRISMA checklist will be used to report findings of the review. We will communicate the findings by publication in a peer-reviewed journal, and by participation in scientific meetings and national and international conferences.

Study status
Study protocol has been completed.
Database search completed.
Title screening completed.
Conducting abstract screening.

Data availability
Underlying data
No underlying data are associated with this article.

Extended data
Harvard Dataverse: Study Characteristics extraction table for a protocol for a systematic review of behaviour change techniques used in the context of stillbirth prevention. https://doi.org/10.7910/DVN/0GCWXX

Reporting guidelines
Harvard Dataverse: PRISMA-P Checklist for “A protocol for a systematic review of behaviour change techniques used in the context of stillbirth prevention”. https://doi.org/10.7910/DVN/6WNOFO

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

References
7. Xiong T, Mu Y, Liang J, et al.: Hypertensive disorders in pregnancy and


Open Peer Review

Current Peer Review Status:  

[Image]

[Image]

Open Peer Review

Current Peer Review Status:  

Version 2

Reviewer Report 24 January 2023

https://doi.org/10.21956/hrbopenres.14760.r33274

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Andrea M. Patey

1 Centre of Implementation Research, Ottawa Hospital Research Institute, Ottawa, ON, Canada
2 School of Epidemiology and Public Health, University of Ottawa, Ottawa, ON, Canada

The Authors provide a detailed protocol to identify all behavioural interventions with a behavioural component designed and trialled for the prevention of stillbirth in high-income countries, and to identify the behaviour change techniques (BCTs) used in such interventions using the Behaviour Change Techniques Taxonomy V1 (BCTTv1). They efficiently provide rationale for this review in that there has not been a systematic review of behaviour change interventions conducted in the context of stillbirth prevention. The Authors argue that the review is important to understand what techniques have been used previous to inform the development of theoretically robust evidence based interventions.

I believe that the authors have appropriately addressed concerns raised by previous reviewers and have provided strong methods for their investigation to address their proposed objectives. I have no major or minor concerns with the protocol.

Is the rationale for, and objectives of, the study clearly described?  
Yes

Is the study design appropriate for the research question?  
Yes

Are sufficient details of the methods provided to allow replication by others?  
Yes

Are the datasets clearly presented in a useable and accessible format?  
Yes

Competing Interests: No competing interests were disclosed.
Reviewer Expertise: Implementation science, behaviour science and health psychology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 22 April 2022

https://doi.org/10.21956/hrbopenres.14760.r31640

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Rae Thomas
Institute for Evidence-Based Healthcare, Bond University, Gold Coast, Australia

Thank you to the authors for providing clarity to my queries. I am happy with the authors' responses.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have conducted multiple systematic reviews and have used BCTs and implementation strategies to design interventions.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
Thank you for the opportunity to review this systematic review protocol. The authors are hoping to identify behavioural intervention to prevent still birth and determine whether these interventions used behaviour change techniques. It is a very interesting topic and I wish the authors well. I have a few comments for them to consider and hope the review is not too far along for these comments to be of assistance.

Introduction:
It was difficult to ascertain the necessity for this review from the introduction. The authors rightly mention there are already interventions that target some of the modifiable risk factors associated with still birth but that the results from a Cochrane review of 61 different still birth approaches conducted in 2020 found discrepancies across different settings. This was justified as a need to understand an intervention’s context. Does this mean different countries? The authors also mention published studies that specifically explore barriers and facilitators that influence health behaviours during pregnancy.

I assume this systematic review is a likely precursor to an intervention trial. If this is the case, I am not sure the argument has been made that this new systematic review is different to other reviews or adds extra information. Could the authors not extract the studies from the Cochrane review that relate to ‘high income countries’, identify the BCTs in these studies and then use the barriers and facilitator studies to create a logic model for some intervention trials of identified modifiable behaviours?

Methods:
Why would the authors be interested in searching for Guidelines (line 33 of search strategy) for an intervention question?

What is the justification of including most study designs (lines 25-31)? All study designs in the search strategy have comparison groups but the cross-sectional design in the eligibility criteria does not. How is this reconciled? If the authors are inclusive of all designs, do not add them to the search strategy.

What is “initiative” (line 32)?

Conducting a forward citation search of included studies would be beneficial.

What proportion of data extraction will be “verified for accuracy”? I notice the coding of BCTs (present/absent) is elsewhere, but wouldn’t this happen at the data extraction phase?

The EPOC risk of bias is appropriate for studies with a control group but what about the cross-
section study design mention in the eligibility section? How many authors will independently conduct the RoB assessment?

I do not understand how you would conduct a meta-analysis of presence or absence of BCTs regardless of high heterogeneity. Do the authors mean that they would examine the presence or absence of BCTs within the context of intervention effectiveness? Would it be the number of BCTs used?

I apologise that I am unclear about the purpose and outcome of this protocol.

**Is the rationale for, and objectives of, the study clearly described?**
No

**Is the study design appropriate for the research question?**
Partly

**Are sufficient details of the methods provided to allow replication by others?**
No

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

*Competing Interests:* No competing interests were disclosed.

*Reviewer Expertise:* I have conducted multiple systematic reviews and have used BCTs and implementation strategies to design interventions.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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**Author Response 07 Mar 2022**

**Tamara Escanuela Sanchez**

Thank you for taking the time to review our protocol and suggest improvements.

**Reviewer comment 2.1:**
It was difficult to ascertain the necessity for this review from the introduction. The authors rightly mention there are already interventions that target some of the modifiable risk factors associated with still birth but that the results from a Cochrane review of 61 different still birth approaches conducted in 2020 found discrepancies across different settings. This was justified as a need to understand an intervention's context. Does this mean different countries? The authors also mention published studies that specifically explore barriers and facilitators that influence health behaviours during pregnancy.

**Response to comment 2.1:**
The focus of this review is to explore interventions that have a behavioural change component, targeting known modifiable risk factors for stillbirth and learning what the components of these interventions are.

We aim to gather enough evidence and theoretical foundations to inform the development of a behaviour change intervention that has an impact on stillbirth prevention. Hence, the objective of this review is to understand behaviour change techniques have been used so far in the context of stillbirth prevention interventions with a behaviour change component.

We do not aim to look at differences between countries, but to focus on high-income settings in order to gather evidence relevant to the context of the review.

**Reviewer comment 2.2:**
I assume this systematic review is a likely precursor to an intervention trial. If this is the case, I am not sure the argument has been made that this new systematic review is different to other reviews or adds extra information. Could the authors not extract the studies from the Cochrane review that relate to ‘high income countries’, identify the BCTs in these studies and then use the barriers and facilitator studies to create a logic model for some intervention trials of identified modifiable behaviours?

**Response to comment 2.2:**
The aim of this review is to explore behaviour change interventions targeting modifiable risk factors for stillbirth.

The Cochrane review has a broader objective than the our review, as it looked at a range of interventions, not just those with a behavioural focus. To date, there has not been any systematic review of behaviour change interventions conducted in the context of stillbirth prevention. Such a review is needed to understand what techniques have been used previously to inform the development of theoretically robust evidence based interventions.

We are aware of and acknowledge the usefulness of the Cochrane review and anticipate that interventions included in the Cochrane review will also be identified in our search. However, the search proposed in our review will also enable us to identify additional studies published since the Cochrane review search, in addition to any additional, specific behaviour change interventions relevant to stillbirth. We will manually check all of the interventions included in systematic reviews identified in our search – included the named Cochrane review-to ensure that all potentially relevant interventions are included. We consider then that relying on the Cochrane review only would not meet our aims due to the aim of the review to provide a comprehensive up-to-date review of interventions including behavioural components to prevent stillbirth.

We have added further explanation to our introduction section to clarify this point further (Page 3, paragraph 2):

*Further, this Cochrane review of reviews had a focus on a broad range of interventions (i.e., nutritional interventions, prevention and management of infection, prevention and management of morbidities, screening and management of fetal growth), not only those with a behaviour*
change component. To date, there has not been any systematic review of behaviour change interventions conducted in the context of stillbirth prevention. Hence, this review is important to understand what techniques have been used previous to inform the development of theoretically robust evidence based interventions.

**Reviewer comment 2.3:**
Why would the authors be interested in searching for Guidelines (line 33 of search strategy) for an intervention question?

*Response to comment 2.3:*
Guidelines are included in our search strategy because we hypothesised that guidelines may include stillbirth prevention strategies involving behaviour components that are targeted at population level.

**Reviewer comment 2.4:**
What is the justification of including most study designs (lines 25-31)? All study designs in the search strategy have comparison groups but the cross-sectional design in the eligibility criteria does not. How is this reconciled? If the authors are inclusive of all designs, do not add them to the search strategy.

*Response to comment 2.4:*
As we are being inclusive of public health guidelines and other population level approaches, such as public health campaigns, it is appropriate to include cross-sectional study designs. This is because, such approaches to stillbirth prevention at population level cannot easily be examined using experimental approaches and so may necessitate approaches such as cross-sectional studies.

**Reviewer comment 2.5:**
What is “initiative” (line 32)?

*Response to comment 2.5:*
The term ‘initiative’ is operationalised in the current review as a plan or program that is intended to solve a problem. For example, the RCOG’s Each Baby Counts initiative which is a national quality improvement program to reduce the number of babies who die.

https://www.rcog.org.uk/eachbabycounts

We have added this term to our search to be inclusive of population level approaches, as noted previously.

**Reviewer comment 2.6:**
Conducting a forward citation search of included studies would be beneficial.

*Response to comment 2.6:*
Thank you for your suggestion. We will conduct a forward citation search of included studies. This has now been added to the protocol manuscript (page 8, 1rst paragraph):

*When identifying systematic reviews, a manual search of the included interventions will be*
conducted to ensure that all relevant interventions are included in this review. We will also perform a further manual citation search of included studies. Discrepancies will be resolved through consensus discussion and/or recourse to a third reviewer.

**Reviewer comment 2.7:**
What proportion of data extraction will be “verified for accuracy”? I notice the coding of BCTs (present/absent) is elsewhere, but wouldn't this happen at the data extraction phase?

**Response to comment 2.7:**
50% of the data extraction process will be verified by a senior researcher (KMS). If any issues of discrepancies are observed, the rest of the data extraction will also be checked for accuracy.

The last phase of our screening process, which involves a very detailed exploration of the study using our inclusion and exclusion criteria, will also lead to discard some of the interventions.

The BCT coding will be conducted afterwards on the interventions that meet our inclusion criteria. BCT coding forms the data synthesis phase of the review, whereby we will use the data extracted on the interventions used to code for behaviour change techniques. Coding is not done therefore during the data extraction phase because it is the next systematic stage of the review.

**Reviewer comment 2.8:**
The EPOC risk of bias is appropriate for studies with a control group but what about the cross-section study design mention in the eligibility section? How many authors will independently conduct the RoB assessment?

**Response to comment 2.8:**
The EPOC risk of bias tool assessing both randomised trials (and/or non-randomised trials and/or controlled before-after (CBA) studies) and interrupted time series (ITS) studies.

Thank you for bringing that point up to our attention. After consideration, we have decided that the JBI critical appraisal checklist for both descriptive and analytical cross-sectional studies.

Two authors will independently conduct the quality assessment.

**Reviewer comment 2.9:**
I do not understand how you would conduct a meta-analysis of presence or absence of BCTs regardless of high heterogeneity. Do the authors mean that they would examine the presence or absence of BCTs within the context of intervention effectiveness? Would it be the number of BCTs used?

**Response to comment 2.9:**
A meta-analysis study can not be conducted due to the heterogeneity of the interventions in terms of target behaviour, outcomes and BCTs used. We anticipate that trying to merge
multiple behaviours and constructs, from a possibly small number of trials to fit into categories for a meta-analysis, would not provide reliable results into effectiveness. We apologise for the lack of clarity, we have revised the manuscript to further clarify this.

We will examine the presence or absence of BCTs by coding the different elements of the interventions into the BCTTv1 taxonomy. Hence, we will not only provide information on the total number of BCTs used in each intervention but also on which specific BCTs have been used.

The effects of the interventions for each behaviour will be summarised and presented briefly. The frequency of BCTs used in the context of effective or non-effective interventions will be presented in a tabular format and examined narratively.

**Reviewer comment 2.10:**
I apologise that I am unclear about the purpose and outcome of this protocol.

**Response to comment 2.10:**
We hope these clarifications and addition to the manuscript have clarified the purpose and outcomes of this study. Thank you for your comments.

**Competing Interests:** No competing interests were disclosed.
2. The main aim of this review, based on the rationale, is to understand which BCTs would be useful to replicate in future interventions or to utilize in routine settings. Yet, this is not clear from the objectives. Only reporting which BCTs were used answers half of the question. We need to understand which is more likely to work. Also, if the aim is to understand effectiveness, then including intervention studies would only be suitable.

3. The focus on different behaviours that might provide benefits in preventing stillbirth requires a subgroup analysis of these behaviours and which BCTs work for each.

4. The others mentioned applying for PROSPERO, I suggest updating this protocol based on their reviews and add the registration number as well.

5. A meta-analysis and a meta-regression would be useful to examine the effectiveness of these interventions and BCTs in reducing stillbirths.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Behaviour change and disease prevention

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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**Author Response 07 Mar 2022**

**Tamara Escanuela Sanchez**

Thank you for taking the time to review and provide feedback on our protocol paper.

**Reviewer comment 1.1:**
The inclusion of high-income countries only is not well justified, the authors mention the differences in healthcare systems, however, due to the focus on health behaviours in this review, a clearer justification is needed. Or a reconsideration of including low and middle-income countries.
Response to comment 1.1:
Thank you for your comment.
We appreciate the relevance of identifying interventions used in middle- and low-income countries. However, even though we are exploring health behaviours in this review, the main focus is associated with stillbirth prevention.

The challenges associated with decreasing the rates of stillbirth in middle- and low-income countries are very different to those in high-income countries as the local health systems context is crucial for preventing stillbirth. 98% of the stillbirths occurred every year are in low- and middle-income countries, and 55% of those are in rural families where skilled attendance and caesarean sections are much lower than for urban births (Lawn et al., 2011). We also know from the data exposed in the stillbirth series published in the Lancet in 2011, that in high-income countries, intrapartum stillbirth rates are typically less than 0.5 per 1000 total births, compared with rates of 12 per 1000 total births in many middle- and low-income countries. According to the authors, most of the babies who die during labour are term babies whose deaths are often associated with suboptimal care. To prevent antepartum stillbirth, improved maternal health ad care during pregnancy is needed, whereas to prevent intrapartum stillbirths, better obstetric care is necessary (Lawn et al., 2011).

Hence, given these differences, we consider that different reviews for the different contexts should be conducted to provide contextually relevant information that might be used to inform the development of future interventions. In our case, and given the scope and aims of our project, we made the decision of investigating high-income counties.

Reviewer comment 1.2:
1.2 The main aim of this review, based on the rationale, is to understand which BCTs would be useful to replicate in future interventions or to utilize in routine settings. Yet, this is not clear from the objectives. Only reporting which BCTs were used answers half of the question. We need to understand which is more likely to work. Also, if the aim is to understand effectiveness, then including intervention studies would only be suitable. A meta-analysis and a meta-regression would be useful to examine the effectiveness of these interventions and BCTs in reducing stillbirths. The focus on different behaviours that might provide benefits in preventing stillbirth requires a subgroup analysis of these behaviours and which BCTs work for each.

Response to comment 1.2:
We anticipate that the availability of data and the heterogeneity of outcomes, interventions and BCTs that the different reviewed papers explore would not allow strong statements about intervention effectiveness similar to a meta-analysis.

Further, we consider that attempting to collapse multiple behaviours and constructs, from a potentially small number of trials, into categories for inclusion in a meta-analysis would not provide reliable results into intervention effects.

As intervention effectiveness is not the main focus of this review, effects of interventions for each behaviour will be presented in table format and briefly narratively.
summarised. Intervention effects will be presented in terms of effect sizes where reported and/or as calculated from data presented within the reviewed papers.

**Reviewer comment 1.3:**
The others mentioned applying for PROSPERO, I suggest updating this protocol based on their reviews and add the registration number as well.

**Response to comment 1.3:**
Protocol has been updated according to PROSPERO reviews and registration ID has been added, thank you. Page 4 Section protocol:

*Details of this review have been submitted for registration to the PROSPERO database (ID CRD42021264914).*

**Competing Interests:** No competing interests were disclosed.